K100078

FEB 12 2010

Boston Scientific Corporation CONFIDENTIAL

510(k) Summary for Modified Straight Fire Laser Fiber

A. Sponsor

Boston Scientific Corporation
Urology and Women's Health Division
100 Boston Scientific Way
Marlborough, MA 01756

B. Contact

Janet A. McGrath
Specialist, Regulatory Affairs
508-683-4726
or
Donna Gardner
Director, Regulatory Affairs
508-683-4398

C. Device Name

Trade name:	To Be Determined *Although the Trade Name is to be determined, for purposes of this submission the proposed device will be referred to as the Modified Straight Fire Laser Fiber
Common/usual name:	Laser Instrument, Surgical, Powered
Classification Name:	GEX – Laser surgical instrument for use in general and plastic surgery and in dermatology 21 CFR 878.4810, Class II

D. Predicate Device(s)

Trade name:	Straight Fire Holmium Laser Fiber
Common/usual name:	Laser Instrument, Surgical, Powered
Classification Name:	GEX – Laser surgical instrument for use in general and plastic surgery and in dermatology 21 CFR 878.4810, Class II
Premarket Notification:	Boston Scientific; K082928

Trade name:	SlimLineEZ™ Laser Lithotripsy Fibers
Common/usual name:	Laser Instrument, Surgical, Powered
Classification Name:	GEX – Laser surgical instrument for use in general and plastic surgery and in dermatology 21 CFR 878.4810, Class II
Premarket Notification:	Lumenis; K011703

E. Device Description

The proposed modified Straight Fire Laser Fiber is a fiber optic laser energy delivery device consisting of a silica core fiber jacketed with ethelylene tetraflouroethylene (ETFE) and a SMA 905 connector. It is equipped with a polished, flat output tip. This fiber may be used in a variety of laser based surgical cases as an integral part of laser systems.

For use with holmium (Ho:YAG) and neodymium (Nd:YAG) lasers with a standard SMA 905 connector that have been cleared for surgical use. Recommended lasers are Lumenis VeraPulse® PowerSuite™ Laser Systems.

F. Intended Use

The Straight Fire Laser Fiber is designed for use with Ho:YAG and Nd:YAG lasers for indications that are cleared for these laser systems, including, but not limited to endoscopic, laparoscopic, and open surgical procedures involving vaporization, ablation, coagulation, hemostasis, excision, resection, incision of soft and cartilaginous tissue, and fragmentation of urinary and biliary calculi (Ho:YAG wavelength only). The fiber is designed for use with a standard SMA-905 connector that have been cleared for surgical use.

G. Technological Characteristics

The proposed modified Straight Fire Laser Fiber has the same technological characteristics (i.e. SMA 905 connector, length of fiber connector type, fiber core, and strain relief) as the predicate device.

H. Substantial Equivalence

Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" a direct comparison of key characteristics demonstrates that the proposed laser fiber is substantially equivalent to the predicate device in terms of intended use, technological characteristics, and performance characteristics. The proposed modified Straight Fire Laser Fiber is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 12 2010

Boston Scientific Corp.
% Intertek Testing Services
Mr. Daniel W. Lehtonen
2307 East Aurora Road Unit B7
Twinsburg, Ohio 44087

Re: K100078
Trade/Device Name: Modified Straight Fire Laser Fiber
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgerical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: February 2, 2010
Received: February 3, 2010

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if Known): K100078

Device Name: Undetermined

Indications For Use:

The Straight Fire Laser Fiber is designed for use with Ho:YAG and Nd:YAG lasers for indications that are cleared for these laser systems, including, but not limited to endoscopic, laparoscopic, and open surgical procedures involving vaporization, ablation, coagulation, hemostasis, excision, resection, incision of soft and cartilaginous tissue, and fragmentation of urinary and biliary calculi (Ho:YAG wavelength only). The fiber is designed for use with a standard SMA-905 connector that have been cleared for surgical use.

Prescription Use __X__ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K100078